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April 24, 2020

VIA ECF

The Honorable Douglas E. Arpert, U.S.M.J.
United States District Court
Clarkson S. Fisher Fed. Bldg. & U.S. Courthouse
402 East State Street
Trenton, NJ 08608

Re: Par Pharm., Inc. et al. v. Sandoz Inc.
Civil Action No. 3:18-cv-14895-BRM-DEA

Dear Judge Arpert:

This firm, together with Brinks Gilson & Lione, represents Defendant Sandoz Inc. ("Sandoz") in the above-captioned suit. Sandoz respectfully requests leave to amend its invalidity contentions in view of recently-discovered prior art. Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par") do not oppose Sandoz's request.

The amendments to Sandoz's invalidity contentions are directed to a prior art product sold by American Regent, Inc. ("American Regent"). Sandoz recently obtained information regarding the American Regent product through third-party discovery that Sandoz served on American Regent in February 2020 and American Regent responded to in March 2020. Good cause exists for Sandoz's proposed amendments under Local Patent Rule 3.7 because Sandoz diligently sought leave to amend its contentions and because the amendments will not cause any prejudice to Par.

Sandoz's amended invalidity contentions contain confidential information and Sandoz will provide a copy to the Court at the Court's request. A proposed order granting Sandoz leave to amend is attached as Exhibit A.

I. GOOD CAUSE EXISTS FOR SANDOZ'S AMENDED INVALIDITY CONTENTIONS.

Leave to amend infringement contentions may be granted "by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. Good cause "considers first whether the moving party was diligent in amending its contentions and then whether the non-moving party would suffer prejudice if the motion to amend were granted." *AstraZeneca AB v. Dr. Reddy's Labs., Inc.*, No. 11-2317, 2013 U.S. Dist. Lexis 36779, at *8 (D.N.J. Mar. 18, 2013). This Court has recognized that "Rule 3.7 'is not a straitjacket into which litigants are locked from the moment their contentions are served.'" *TFH Publ'ns, Inc. v. Doskocil Mfg. Co.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010) (permitting amendment).

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In late 2019, Sandoz became aware that a prior art product sold by American Regent may be relevant to the validity issues in this case. Sandoz contacted American Regent in December 2019 and American Regent responded in January 2020 by indicating it would not produce the requested documents absent a subpoena, which Sandoz served on February 13, 2020. American Regent completed its production of information in response to the subpoena on March 13, 2020. On April 1, 2020, Sandoz informed Par that it would request leave to amend its invalidity contentions and sent the proposed amended invalidity contentions to Par. On April 20, 2020, Par stated that it does not oppose Sandoz's proposed amendments to the invalidity contentions.

Both the Local Patent Rules and the case law interpreting those rules recognize that Sandoz should have the opportunity to amend its contentions to advance theories of invalidity based on this newly discovered prior art. Local Patent Rule 3.7 provides a non-exhaustive list of examples that may support a finding of good cause, including "recent discovery of material prior art despite earlier diligent searches." *Amgen Inc. v. Kashiv Biosciences, LLC*, No. 18-3347, 2019 U.S. Dist. Lexis 183789, at *6 (D.N.J. Oct. 24, 2019). "[D]iligence is not 'a draconian requirement of perfection and clairvoyance.'" *Abraxis BioScience, LLC v. Actavis, LLC*, No. 16-1925, 2017 U.S. Dist. Lexis 73400, at *7 (D.N.J. May 15, 2017). Sandoz diligently sought discovery of the prior art vasopressin formulation sold by American Regent and Sandoz promptly sought leave to amend its contentions. On these facts, Sandoz acted diligently and has demonstrated good cause to amend its invalidity contentions. *See Abraxis BioScience*, 2017 U.S. Dist. 73400, at *9 (determining that a delay of about four months to review, investigate, prepare, and serve amended contentions is "timely").

II. PLAINTIFFS WILL NOT BE PREJUDICED BY THE PROPOSED AMENDMENTS.

The proposed amendments will have no effect on the deadlines in this case. Fact discovery is still open and opening expert reports have been postponed. *See Amgen*, 2019 U.S. Dist. Lexis at *8. For at least these reasons, Sandoz's amended contentions would not cause any prejudice to Par. Par has confirmed that they do not oppose Sandoz's proposed amended contentions.

* * *

Because Sandoz diligently sought to amend its contentions, and because those contentions will not prejudice Plaintiffs, good cause exists for Sandoz's proposed amendments to its invalidity contentions.

For the foregoing reasons, Sandoz respectfully requests that the Court enter the order attached as Exhibit A granting Sandoz leave to amend. Thank you for Your Honor's kind attention to this matter.

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Respectfully submitted,

/s/ Eric I. Abraham
ERIC I. ABRAHAM

cc: All Counsel of Record (via ECF and e-mail)